

CLAIMS

1. A solution wherein a high concentration of immunoglobulin is stabilized, and wherein the immunoglobulin is IgM.
- 5 2. The solution of claim 1, comprising IgM at a concentration higher than 1 mg/mL.
3. The solution of claim 1, which is an aqueous solution.
- 10 4. The solution of claim 1, which is a pharmaceutical formulation.
5. The solution of claim 1, comprising a polyvalent cationic ion.
6. The solution of claim 5, comprising the polyvalent cationic ion at a concentration of 1 mM
15 to 1,000 mM.
7. The solution of claim 5, wherein the polyvalent cationic ion is a Mg ion or an Arg ion.
8. The solution of claim 5, further comprising sugars.
- 20 9. The solution of claim 1, which is pH5 to pH8.
10. The solution of claim 1, wherein the solution does not intrinsically comprise human-derived proteins other than IgM.
- 25 11. The solution of claim 1, wherein the solution does not intrinsically comprise proteins other than IgM.
12. A pharmaceutical formulation obtained by freezing or lyophilizing the solution of any one
30 of claims 1 to 11.
13. A method for stabilizing a solution comprising a high concentration of immunoglobulin, wherein the immunoglobulin is IgM and wherein the method comprises adding a polyvalent cationic ion to the solution.
- 35 14. The method of claim 13, wherein the solution comprises IgM at a concentration higher than

1 mg/mL.

15. The method of claim 13, wherein the solution is an aqueous solution.

5 16. The method of claim 13, wherein the solution is a pharmaceutical formulation.

17. The method of claim 13, which comprises adding a polyvalent cationic ion to the solution such that the solution comprises the polyvalent cationic ion at a concentration of 1 mM to 1,000 mM.

10 18. The method of claim 13, wherein the polyvalent cationic ion is a Mg ion or an Arg ion.

19. The method of claim 13, further comprising addition of sugars.

15 20. The method of claim 13, wherein the pH of the solution is 5 to 8.

21. The method of claim 13, wherein the solution does not intrinsically comprise human-derived proteins other than IgM.

20 22. The method of claim 13, wherein the solution does not intrinsically comprise proteins other than IgM.

23. A method for stabilizing a pharmaceutical formulation, which comprises the steps of:

(a) performing the method of any one of claims 13 to 22; and

25 (b) freezing or lyophilizing the solution stabilized in step (a).

24. A method for producing a solution comprising a high concentration of stabilized immunoglobulin, wherein the immunoglobulin is IgM and wherein the method comprises the step of adding a polyvalent cationic ion to the solution.

30 25. The method of claim 24, wherein the solution comprises IgM at a concentration higher than 1 mg/mL.

26. The method of claim 24, wherein the solution is an aqueous solution.

35 27. The method of claim 24, wherein the solution is a pharmaceutical formulation.

28. The method of claim 24, which comprises the step of adding a polyvalent cationic ion to the solution such that the solution comprises the polyvalent cationic ion at a concentration of 1 mM to 1000 mM.

5

29. The method of claim 24, wherein the polyvalent cationic ion is a Mg ion or an Arg ion.

30. The method of claim 24, which further comprises the step of adding sugars.

10 31. The method of claim 24, wherein the pH of the solution is 5 to 8.

32. The method of claim 24, wherein the solution essentially does not comprise human-derived proteins other than IgM.

15 33. The method of claim 24, wherein the solution essentially does not comprise proteins other than IgM.

34. A solution which is produced by the method of any one of claims 24 to 33.

20 35. A method for producing a pharmaceutical formulation, wherein the method comprises the steps of:

- (a) performing the method of any one of claims 24 to 33; and
- (b) freezing or lyophilizing the solution produced in step (a).